In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-1883V UNPUBLISHED

FRANCES A. VACCARO,

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: July 19, 2021

Special Processing Unit (SPU); Findings of Fact; Onset and Site of Vaccination; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Wes Baker Allison, Kahn Law Firm, LLP, Charleston, SC, for Petitioner.

Lara Ann Englund, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On December 12, 2019, Frances A. Vaccaro filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine received on October 2, 2018. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

¹ Because this unpublished fact ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the fact ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find that a preponderance of the evidence supports the determination that Petitioner's flu vaccine was administered on October 2, 2018 in Petitioner's left deltoid, and that her onset of pain occurred within the 48-hour post-vaccination timeframe set by the Table.

I. Relevant Procedural History

Following the initial status conference on March 2, 2020, Respondent was directed to file a status report providing counsel's informal reaction to the claim (ECF No. 11). Respondent did so on April 27, 2020 (ECF No. 12), noting that the site of Petitioner's vaccination was not recorded in the records filed. Respondent added that "any uncertainty about the site of administration is compounded by the fact that [P]etitioner did not seek medical treatment for three months after the vaccination." Respondent's April 27, 2020 Status Report at 1. Thereafter, on June 4, 2020, a telephonic status conference was held to discuss how the parties wished to address such fact disputes. Scheduling Order, issued June 4, 2020 (ECF No. 13).

Subsequently, Petitioner filed additional evidence, Exhibits 14-18 (ECF Nos. 14-15). On August 13, 2020, another telephonic status conference was held. Following the conference, I issued a scheduling order stating my preliminary view that a preponderance of the evidence appeared to establish that the flu vaccine at issue had likely been administered in Petitioner's left deltoid. Scheduling Order, issued Aug. 14, 2020 (ECF No. 18). I instructed Respondent to take this preliminary view into account, and indicated that if Respondent had not provided his litigation position or indicated the potential for settlement by the one year mark (measured from the date this case left OSM's preassignment review process), the case faced transfer from SPU, and that I also might decide onset on the written record. *Id.* at *3-4. Petitioner was directed to serve a demand. *Id.* at *4.

On September 9, 2020, Petitioner reported that she had served a demand the day before (ECF No. 19). On November 2, 2020, however, Respondent filed a status report indicating that he had not yet determined his position (ECF No. 20).

On December 11, 2020, Petitioner filed a motion for a ruling on the written record (ECF No. 23). On March 26, 2021, Respondent filed a response asserting that Petitioner's motion should be denied and the Petition should be dismissed. Respondent's Response, filed Mar. 26, 2021 (ECF No. 26). Respondent took the position that the medical records did not establish the site of vaccine administration, and there were no contemporaneous medical records documenting that Petitioner's symptoms began within 48 hours after vaccination. *Id.* at *5.

II. Issue

At issue is whether (a) Petitioner received the vaccination alleged as causal in her injured left arm, and (b) Petitioner's first symptom or manifestation of onset (specifically pain) occurred within 48 hours after vaccine administration as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a) XIV.B. (2017) (influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of*

Health & Hum. Servs., 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." § 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make the below findings after a complete review of the record, including all medical records, affidavits, Respondent's Rule 4 Report, and additional evidence filed. Specifically, I base the findings on the following evidence:

- On October 2, 2018, Petitioner was seen by her primary care provider, Dr. Mary Little
 of Harth Place Family Medicine, for a lump on her foot. Ex. 2 at 4. The record indicates
 that a flu vaccine was also administered during this visit. Id.
- Petitioner's insurer paid Dr. Little \$95.02 for the October 2, 2018 visit, including \$17.34 for a flu vaccine and \$19.07 for administration of a flu vaccine (thus corroborating the fact of the vaccine's administration). Ex. 18 at 1-2.

- On January 3, 2019, Petitioner returned to Dr. Little reporting a cough and left arm pain from her flu shot in October. Ex. 6 at 302-03. The record indicates that Petitioner "[h]ad flu shot in left deltoid 'still sore.' " *Id*.
- On January 18, 2019, Petitioner was seen by orthopedist Dr. James Spearman for left shoulder pain. Ex. 7 at 18-20. The record lists an onset date of October 18, 2018, and indicates that "on 10/18/2018 she got a flu shot and since that time she has had persistent pain and worsening ROM [range of motion]." Id. at 19. While the record lists an incorrect vaccination date, it lists the same date as the date of onset of symptoms and relates onset to the flu shot, suggesting that onset occurred on the date of vaccination.
- On January 29, 2019, Petitioner returned to Dr. Spearman. Ex. 7 at 15-18. The record of this visit incorrectly indicates that her flu vaccine was administered on November 9, 2018. *Id.* at 16. However, it also lists as the date of onset of her left shoulder pain "10/18/18 after flu vaccine." *Id.* at 17.
- On February 26, 2019, Petitioner was seen for a physical therapy initial evaluation.
 Ex. 8 at 82. The date of injury was recorded as February 12, 2019, the date Petitioner underwent shoulder surgery. *Id.* The "Nature of Injury" section states that Petitioner "was given a flu shot in October with the most painful shot, couple weeks was sore and in November was unable to do movements with L arm." *Id.*
- The record also includes a letter dated November 21, 2019 from Dr. Spearman addressed "To Whom It May Concern." Ex. 10. The letter indicates that Petitioner presented to Dr. Spearman's office on January 18, 2019 with left shoulder pain that began after an October 2018 flu shot. *Id.* at 1. Dr. Spearman stated that based on Petitioner's history and presentation, "I suspected adhesive capsulitis as a result of the administration of the flu vaccine. In my opinion, the injection was likely administered too high on the shoulder, causing an inflammatory response that led to the development of scar tissue inside the joint." *Id.* He concluded that in his opinion "all of the treatment that Mrs. Vaccaro received for her left shoulder including surgery on Feb. 12, 2019, was and is directly related to the administration of the flu shot in October 2018." *Id.* at 2.
- Petitioner filed two affidavits in support of her petition. Petitioner averred that on October 2, 2018 she was given a flu shot by a member of Dr. Little's staff "who inserted the needle near the joint at the top of my left shoulder." Ex. 3 at ¶ 3. She explained that she was seated on an exam bench that was against a wall, with her

right shoulder facing the wall and her left shoulder facing the aide who administered the vaccine. Ex. 15 at ¶ 5. She did not use her left arm while driving home from the clinic, and did not try to lift her granddaughter that day due to pain. *Id.* at ¶ 9. Over time, her shoulder gradually worsened and she experienced difficulty using her left arm to move or carry things. *Id.* at ¶¶ 12-13. She took ibuprofen for the pain and assumed it would go away. *Id.* at ¶ 14. Her shoulder gradually worsened, and by Christmas she was unable to reach for items above her head or fasten a bra strap, and needed help to cook. *Id.* at ¶ 14. At her family's insistence, she finally called Dr. Little on December 27, 2018 and was given a January 3, 2019 appointment. *Id.* at ¶ 15.

- Petitioner submitted an affidavit from her husband, Anthony Vaccaro. Ex. 4. He averred that when his wife returned home on October 2, 2018 after her flu shot, she said that the shot had hurt her shoulder and arm. *Id.* at ¶ 3. He explained that her shoulder was obviously sore and stiff, and that it gradually got worse through Thanksgiving. *Id.* at ¶ 3. He stated that his wife is healthy and generally reluctant to see a doctor, so it did not surprise him that she waited to see if her shoulder would improve with time. *Id.* at ¶ 4. However, by Christmas, she was in extreme discomfort and having difficulty carrying heavy objects and reaching overhead and behind her. *Id.* at ¶ 5. At that point, she finally called Dr. Little's office for an appointment. *Id.* at ¶ 5.
- Petitioner submitted an affidavit from her daughter, Nicole Mary Jarvis. Ex. 5. She averred that she lives near her parents and sees her mother three to four times a week. Id. at ¶ 3. She stated that her mother's left shoulder and arm pain and loss of mobility started immediately after vaccination. Id. at ¶ 4. She noticed her mother not being able to put on a bra or jacket or fix her hair. Id. at ¶ 4. The pain and mobility issues got worse around the holidays. Id. at ¶ 6.
- Petitioner submitted an affidavit from her daughter in law, Carissa Vaccaro. Ex. 16. She averred that she lives four houses away from Petitioner and sees her every day. Id. at ¶¶ 5-6. She saw Petitioner the day she received the flu shot and "could tell her left arm was bothering her by the way that she was avoiding using it." Id. at ¶ 7. She noticed increasing stiffness over the next several weeks, and by Thanksgiving Petitioner was draping her jacket over her left shoulder rather than putting her arm in the sleeve. Id. at ¶¶ 9-10. She stated that she kept telling Petitioner to call her doctor about her shoulder, but Petitioner repeatedly said that she did not want to seek treatment during the holidays. Id. at ¶¶ 12-14.

• Petitioner submitted an affidavit from her son, Anthony Vaccaro, who also lives four houses away and sees Petitioner daily. Ex. 17 at ¶¶ 4-5. On the day Petitioner received the flu shot, she came to his house and said that her left arm and shoulder hurt from the shot and felt different than usual. *Id.* at ¶ 6. Over the next two months, he noticed her using her right arm to do things she would normally do with her left arm. *Id.* at ¶ 9. When the weather turned cold, it became difficult for her to put on a jacket and she would arrive at his house with a jacket draped around her shoulders, or with only her right arm in a sleeve. *Id.* at ¶ 11. He stated that she is stubborn and does not like to go to the doctor, but eventually agreed to go after the holidays. *Id.* at ¶ 15-16. By Christmas, he stated that her left arm was "literally just by her side. She wasn't using it for anything." *Id.* at ¶ 17.

I find that the above records, when viewed in their totality, preponderantly establish that Petitioner received a flu vaccine on October 2, 2018. Ex. 2 at 4; Ex. 18 at 1-2. I acknowledge that the record also contains records suggesting alternative dates of administration, e.g., October 18, 2018 (Ex. 7 at 19) or November 9, 2018 (Ex. 7 at 16). However, I find that the record of the October 2, 2018 visit where the vaccine was administered is the best evidence. Ex. 2 at 4. In addition, the evidence demonstrating that Petitioner's insurance paid for a flu vaccine and the administration of the vaccine on that date is strong supporting evidence. Ex. 18 at 1-2.

With respect to the site of administration, the record of the visit where the vaccine was administered is silent on this issue. Ex. 2 at 4. Petitioner obtained her personal immunization record from the state of South Carolina, which has some records for other years but none for 2018. Ex. 14. In addition, the office where the vaccine was administered closed before the petition was filed, and Petitioner was unable to obtain other records concerning the vaccination. Ex. 15 at ¶ 18.

Although there is not a direct contemporaneous medical record documenting the site of vaccine administration, there is evidence shedding light on the matter, and it preponderantly supports a finding that the vaccine was administered in Petitioner's left deltoid. For example, at Petitioner's first appointment for shoulder pain -- a January 3, 2019 appointment with Dr. Little, whose office administered the vaccine -- the record indicates that Petitioner had "L[eft] arm pain from flu shot in Oct." and "Had flu shot in left deltoid . . . still sore." Ex. 6 at 302 (emphasis added). This is compelling evidence supporting a finding that the vaccine was administered in Petitioner's left deltoid.

Then, at subsequent appointments Petitioner consistently informed treaters of left shoulder pain related to her October 2018 flu vaccine. On January 18, 2019, she was seen by orthopedist Dr. Spearman for left shoulder pain and reduced range of motion

"after flu shot in the fall." Ex. 7 at 19. While this record included an incorrect vaccination date, October 18, 2018, it indicated that her left shoulder pain was related to her flu shot. *Id.* A February 26, 2019 physical therapy evaluation also related her left shoulder pain to an October 2018 flu shot. Ex. 8 at 82.

Finally, Petitioner's treating physician, orthopedist Dr. Spearman, opined that Petitioner's left shoulder pain and stiffness, and all treatment including surgery on February 12, 2019 were "directly related to the administration of the flu shot in October 2018." Ex. 10 at 1-2.

I find that the most compelling evidence of the site of administration is the January 3, 2019 record of Petitioner's appointment, in the office where the vaccine was administered, documenting that Petitioner's flu shot was administered in her left deltoid. Ex. 6 at 302. This record, supported by additional medical records, affidavit evidence, and the complete absence of any record evidence suggesting that the vaccine was administered in Petitioner's right arm, leads me to find that the preponderance of the evidence supports a finding that Petitioner's left arm was the site of vaccination.

Respondent also disputes whether the onset of Petitioner's symptoms began within 48 hours of vaccine administration. I find that a preponderance of the evidence indicates that her pain began within that timeframe.

When Petitioner's first reported shoulder pain, she related it to her October 2018 flu shot. Ex. 6 at 302. When she was first seen by her orthopedist, she reported that she had experienced persistent pain and worsening range of motion *since* her flu shot. Ex. 7 at 19 (emphasis added). I acknowledge that the date of vaccination was inaccurately recorded as October 18th in this record. *Id.* However, the record also lists that same date as the date of onset. *Id.* Thus, the information provided to Petitioner's treating orthopedist was that onset occurred on the same day as vaccination. Information provided to medical providers when seeking treatment is considered trustworthy. *Cucuras*, 993 F.2d at 1528.

Respondent emphasizes that Petitioner did not seek treatment for more than three months after vaccination. I acknowledge this, but note that this length of treatment delay is not uncommon in SIRVA cases, and a three-month delay alone is not concerning, especially absent evidence of intervening opportunities to inform relevant treaters of the problem. See, e.g., Winkle v. Sec. of Health & Hum. Servs., No. 20-0845V, 2021 WL 2808993 (Fed. Cl. Spec. Mstr. June 3, 2021) (finding onset occurred within 48 hours in case where first appointment for shoulder pain was nearly five months after vaccination). I find that Petitioner's medical records support a finding of immediate onset, and she has

provided ample affidavit evidence explaining the reasons for her treatment delay, which I find reasonable.

Accordingly, there is preponderant evidence to establish that (a) the vaccine alleged as causal in this case was administered to Petitioner in her left deltoid on October 2, 2018, and (b) the onset of Petitioner's pain occurred within 48 hours of vaccination. Specifically, I find the onset of petitioner's pain immediately upon vaccination. Petitioner's motion is granted to the extent consistent with these findings.

V. Scheduling Order

• Respondent shall file, by no later than <u>Wednesday</u>, <u>August 25, 2021</u>, his Rule 4(c) Report or a status report indicating how he intends to proceed.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master